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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,455	10/10/2003	Jorg Kowalczyk	G5005.0026	9811

32172 7590 12/02/2004

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EXAMINER

HENRY, MICHAEL C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/682,455

**Applicant(s)**

KOWALCZYK ET AL.

**Examiner**

Michael C. Henry

**Art Unit**

1623

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspond nce address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

Art Unit: 1623

### **DETAILED ACTION**

Claims 1-13 are pending in application

#### ***Information Disclosure Statement***

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “after pasteurization the starting components are homogenized in a method step (b)”, in claim 1 renders the claim indefinite. More specifically, it is unclear how the step designated method step (b) can occur after pasteurization which is in step (c). This phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Similarly, claim 2 which recites the phrase “after autoclaving the starting components are homogenized in a method step (b)”, renders the claim indefinite, since it is unclear how the step designated method step (b) can occur after autoclaving which is in step (c).

#### ***Claim Rejections - 35 USC § 103***

Art Unit: 1623

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishio et al. (JP 01191646 A, abstract).

In claim 2, applicant claims a "Method of production of an isomaltulose-containing enteral nutrient including the steps of: (a') providing the starting components water, fat, at least one nitrogen-containing component, and carbohydrate with the inclusion of isomaltulose, and (c') autoclaving the starting components for 5-15 min. at temperatures  $\geq 120$  °C, wherein before or after autoclaving the starting components are homogenized in a method step (b').".

Nishio et al. disclose a method of the production of an isomaltulose-containing enteral nutrient including the steps of: providing the starting components water, fat (a lipid), at least one nitrogen-containing component (a lacto protein), and carbohydrate (another saccharide), palatinose (isomaltulose), and heating this solution at a temperature of 120 °C under normal pressure.

The difference between applicant's claimed method and the method of Nishio et al. is that applicant autoclave and homogenize their composition. However, autoclaving as opposed to heating at the same temperature should only affect the time of heating required and not the product formed, and it is common to homogenize such compositions that are intended for enteral or oral consumption to produce a composition of homogeneous consistency. Furthermore,

Art Unit: 1623

Nishio et al.'s admixes the components of their composition to produce a composition of homogeneous consistency (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use Nishio et al.'s method to produce an isomaltulose-containing enteral nutrient, and to autoclave and homogenize the nutrient depending on availability and/or need, since autoclaving as opposed to heating at the same temperature (at normal pressure) should only affect the time of heating required for the production of the enteral-nutrient composition, and it is common in the art to homogenize such compositions that are intended for enteral or oral consumption.

One having ordinary skill in the art would have been motivated to use Nishio et al.'s method to produce an isomaltulose-containing enteral nutrient, and to autoclave and homogenize the nutrient depending on availability and/or need, since autoclaving as opposed to heating at the same temperature (at normal pressure) should only affect the time of heating required for the production of the enteral-nutrient composition, and it is common in the art to homogenize such compositions that are intended for enteral or oral consumption.

***Allowable subject Matter***

The following is an examiner's statement of reasons for allowance: The examiner has found claims 1 and 3-13 to be unobvious over the prior art of record and therefore may be allowable over the prior art of record provided that the 112 rejection is overcome. The present invention relates to a method of production of an isomaltulose-containing enteral nutrient including the steps of: (a) providing the starting components water, fat, at least one nitrogen-containing component, and carbohydrate with the inclusion of isomaltulose, and (c) pasteurizing

Art Unit: 1623

the starting components for 10-30 seconds at temperatures  $\geq 120^{\circ}\text{C}$ , wherein before or after pasteurizing the starting components are homogenized in a method step (b).” The very relevant prior art documents (JP 01191646 A) to this invention disclose a method of production of an isomaltulose-containing enteral nutrient including the steps of providing the starting components water, fat, at least one nitrogen-containing component, and carbohydrate. However, though the method of the present invention (like that of the prior art document) also relates to the production of an isomaltulose-containing enteral nutrient, the prior art document does suggest nor teach the pasteurizing and homogenizing of said nutrient, and it is neither obvious to pasteurize or homogenize said nutrient especially at the specific claimed time and temperatures.

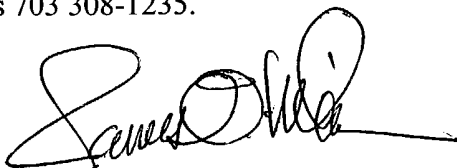
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

November 19, 2004.



JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
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